# 2. MONITORING

Two distinct questions have been raised regarding the use of written action plans in the management of asthma. First, does the use of written action plans make a difference in patient outcomes beyond those accomplished by appropriate medical/pharmacologic management? Second, is there a difference in patient outcomes between action plans based on symptom monitoring and those based on peak flow monitoring? This section of the EPR Update considers both questions.

# WRITTEN ACTION PLANS COMPARED TO MEDICAL MANAGEMENT ALONE

## Question

Compared to medical management alone, does the use of a written asthma action plan improve outcomes?

**Summary Answer to the Question** 

Data are insufficient to support or refute the benefits of using written asthma action plans compared to medical management alone (SRE-Evidence B). Seven studies compared medical management with written action plans to medical management without action plans. Beyond including instructions on the action plan to the intervention groups, four of these studies did not include asthma education for either the intervention or control groups; three of the studies included similar but limited asthma education for both intervention and control groups. Only one study included children. Significant limitations in study designs and methods in these studies preclude conclusions. For example, the studies showing no benefits of written action plans did not have sufficient power for comparisons between treatment and control groups, and the two studies reporting significant improvements with action plans had potential biases in patient selection, withdrawals, data collection, or analysis.

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However, a Cochrane review of 25 studies comparing asthma self-management education interventions for adults to medical care without such education also contrasted those studies with self-management interventions that included written action plans to those that did not. The self-management interventions that included written action plans had the greatest benefits, including reduced emergency department visits and hospitalizations and improved lung function.

The National Asthma Education Prevention Program's (NAEPP's) Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma (EPR-2) recommendations have not been changed: It is the opinion of the Expert Panel that use of written action plans as part of an overall effort to educate patients in self-management is recommended, especially for patients with moderate or severe persistent asthma and patients with a history of severe exacerbations (Evidence B, C).

### **Rationale for the Question**

The use of written action plans is recommended in the EPR-2 and is widely accepted as good practice. Generally, the use of written action plans has been studied as part of self-management education (Gibson et al. 2000). In busy practices, however, physicians often provide their patients with action plans independent of other asthma education efforts. This question was posed in order to identify data that describe the effects of using written action plans, independent of other components of asthma education.

# Systematic Review of the Evidence

The following description of the systematic review of the evidence (SRE) is an adaptation of the evidence report, including direct excerpts, submitted by the Blue Cross Blue Shield Association Evidence-Based Practice Center. (See Introduction, Methods.)

### Methods of Literature Search

For the purpose of the SRE, an action plan is a written algorithm that identifies specific clinical indicators that should alert patients to make adjustments in their medications and provides specific instructions on how to make these adjustments. EPR-2 recommends the use of both a daily self-management plan and an action plan for exacerbations. Generally, studies included in the SRE involved the use of one plan that combined the objectives of both. Typically, the plans divided steps for patient actions into different zones, in which recommended actions are correlated with differing acute signs and symptoms of worsening asthma. Most of the plans in the available studies used four-zone plans, some were threezone plans that did not include directions for use of oral corticosteroids before seeking emergency care.

The evidence review examined studies in which the intervention used an action plan as defined above and, if asthma education was given to both treatment and control groups, the treatment group had no more than 1 additional hour of education for the action plan. The treatment/observation duration was at least 12 weeks, and the intervention

and control groups received the same treatment, except that the intervention group also received a written action plan. Studies were excluded if the comparisons were confounded by additional treatment components in the intervention group—for example, optimization of medications in the intervention group only or education programs of more than 1 hour in the intervention group only. The literature review included randomized controlled trials (RCTs) in which at least 25 evaluable patients (not physicians) were randomly allocated to the intervention and control groups.

# Summary of Findings

### **Studies**

Seven studies involving more than 1,400 patients met SRE inclusion criteria for review; only one of the studies included children. (See the key evidence tables in this section.) None of the studies met SRE standards for high quality; each had significant limitations. None was conducted with sufficient power (i.e., adequate numbers of subjects in each study arm) to enable comparisons between treatment and control groups. In one study reporting reduced emergency department visits, data were unavailable to control for baseline differences that may have existed between treatment and control groups, and the reported effect may be attributed to a subset of high frequency users. In another study, the design involved clinicians who both provided plans and collected assessment data. Moreover, a large number of subjects were excluded from the analyses.

All seven studies compared medical management with written action plans to medical management without written action plans, and all used a peak flow meter-based plan. Three of the studies also included similar but limited asthma education for both the intervention and control groups, but the groups still differed as to whether written plans were used. In two trials, the control group used peak flow meters but without an action plan.

### **Results of Studies**

Five trials documented no differences in outcomes, and two trials documented significant benefit of written action plans, especially in reducing emergency department visits. However, there were notable limitations to each of these trials, as described earlier. In summary, SRE study data were insufficient to support or to refute the advantages of using asthma action plans independent of self-management education when compared with medical management alone.

# Additional Literature/Information

Evidence supporting the use of written plans as a component of self-management education is reported in a recent Cochrane Collaboration review (Gibson et al. 2000). The SRE question on action plans provides a clearer assessment of isolating the advantages of providing an action plan. The Cochrane review centered on the benefits of self-management interventions and regular medical review with the clinician vs. usual medical care. The Cochrane review, however, also contrasted those self-management interventions with written action plans to

those without written action plans. The review included some of the same studies included in the SRE but overcame the limitations of study sample sizes by pooling data. Further, the set of 25 studies in the Cochrane review was larger than the 7 in the SRE due to the broader question under review. In the Cochrane analysis that compared results of self-management interventions with action plans to those without, the interventions with written action plans demonstrated the greatest benefits, including reduced asthmarelated hospital admissions (odds ratio 0.35, 95 percent confidence interval) and reduced emergency department visits (odds ratio 0.55, 95 percent confidence interval). In addition, patients who managed their asthma by adjusting medications according to a written action plan had better lung function than those whose medications were adjusted by a doctor during regular care visits. The review concluded that training in asthma self-management that involves self-monitoring by either peak flow or symptoms, coupled with regular medical review and a written action plan, appears to improve health outcomes for adults with asthma.

Additional evidence supporting written action plans coupled with regular patient education and medical review is available from a recent case control study (Abramson et al. 2001). This study does not fit the SRE review criteria because studies that qualified for this review were required to be RCTs allowing inferences of cause and effect, and they were required to provide an action plan independent of a multicomponent intervention including education. Although the Abramson study is not an RCT, it is a well conducted study that compared 51 patients who died from asthma to 202 patients presenting to hospitals with acute asthma. The study reported that written action plans for patients with severe persistent asthma were associated with a 70-percent reduction in mortality risk. As such, the study supports the opinion that providing written action plans as part of asthma education is an important element of practice.

# **Recommendations for EPR Update**

No data from the SRE, in which RCTs compared written action plans to medical management alone, indicate the need to change the EPR-2 action plan recommendations (SRE-Evidence B). Additional data from studies on action plans as a part of self-management education support the EPR-2 recommendations (Evidence B, C). The following shaded text indicates updated information that should be incorporated into the text on pages 33 and 123 in EPR-2.

# Component 1: Measures of Assessment and Monitoring; Periodic Assessment and Monitoring (page 33 in EPR-2)

Whether peak flow monitoring, symptom monitoring, or a combination of approaches is used, the Expert Panel believes that self-monitoring is important to the effective self-management of asthma. The nature and intensity of self-monitoring should be individualized, based on such factors as asthma severity, patient's ability to perceive airflow obstruction, availability of peak flow meters, and patient preferences.

It is the opinion of the Expert Panel that, regardless of the type of monitoring used, patients should be given a written action plan and instructed to use it. (See figure 4–5.) It is the opinion of the Expert Panel that including action plans as part of an overall effort to educate patients in self-management is the soundest approach and is especially indicated for patients with moderate or severe persistent disease or a history of severe exacerbations (Evidence B, C). It is the opinion of the Expert Panel that a plan is important in large part because it enhances clinician-patient communication. The plan should define a regimen that meets the medical needs of the patient and should have a format that facilitates the patient's understanding and ability to take appropriate action to control the disease. Regardless of format, an effective plan should include the following:

- Explicit, patient-specific recommendations for environmental control and other preventive efforts that
  may be necessary to avoid or reduce the impact of
  exacerbations
- An algorithm of procedures that clearly describes how to use long-term-control and rescue medicines, given a set of specific circumstances and conditions, and clear instructions on how to make medicine adjustments when conditions change
- Steps the patient should take when medicines are ineffective or if an emergency situation arises
- · Contacts for securing urgent care, if needed

As emphasized above, it is the opinion of the Expert Panel that a written action plan is considered part of ongoing efforts to provide self-management education and support appropriate to the severity of the patient's asthma, the patient's age, and related circumstances (Evidence B, C). The clinician should periodically review the plan, revise it as necessary, and confirm that the patient knows what to do if his or her asthma gets worse.

# Component 4: Education for a Partnership in Asthma Care, Key Points (page 123 in EPR-2)

- Patient education should begin at the time of diagnosis and be integrated into every step of clinical asthma care.
- It is essential that education be provided by all members of the health care team. The principal clinician should introduce the key educational messages and negotiate agreements with patients; these messages should be reinforced and expanded by all members of the health care team.
- Teach asthma self-management, tailoring the approach to the needs of each patient. Maintain a sensitivity to cultural beliefs and practices.
- Teach and reinforce at every opportunity:
  - Basic facts about asthma
  - Roles of medications
  - Skills: inhaler/spacer/holding chamber use, self monitoring
  - Environmental control measures
  - When and how to take rescue actions.
- Jointly develop treatment goals.
- To encourage an active partnership, provide all

patients with a written daily self-management plan and an action plan for exacerbations. A written action plan is considered part of ongoing efforts to provide self-management education and support appropriate to the severity of the patient's asthma, the patient's age, and related circumstances (Evidence B, C). Action plans are especially important for patients with moderate-to-severe asthma and patients with a history of severe exacerbations. Provide appropriate patients with a daily asthma diary.

 Encourage adherence by promoting open communication; individualizing, reviewing, and adjusting plans as needed; emphasizing goals and outcomes; and encouraging family involvement.

# **Recommendations for Future Research**

Research that may enhance the quality and effect of interventions fostering patient self-management would examine the following questions:

- Are some action plan formats more effective than others? What characterizes the most effective format?
- What alternative action plan formats are effective, given specific patient needs, including disease severity, literacy levels, languages spoken, ages, and unique management problems (e.g., comorbidities)?
- How much time and emphasis should be given to the development of action plans during the course of clinical counseling? In comprehensive education programs? In medical review?
- What are potential means of providing self-management interventions that include action planning to patients who are members of underserved populations (e.g., reaching them through worksites, community centers, or churches)?
- How effective are written action plans in treating children with asthma?
- How effective are written action plans in different caretaker situations (e.g., day care, camps, or school)?

Tx Setting: Specialty care, nonuniversity

# **Key Evidence Tables**

TABLE 2-1. Study Characteristics

Citation	Study Design	Study Setting
Optimal medical management vs. opt	imal medical management + peak fl	ow meter (PFM)-based action plan
Jones, Mullee, Middleton, et al., 1995  Drummond, Abdalla, Beattie, et al., 1994	Randomized; parallel, controlled  Randomized; parallel, controlled	Country: United Kingdom Funding: Pharm. ind. grant Tx Setting: Primary/specialty combination, university Multicenter Country: United Kingdom
(GRASSIC)	Kandomized, paraner, controlled	Funding: Academic grant Tx Setting: Specialty care, nonuniversity Multicenter
Ayres, Campbell and Follows, 1995	Randomized; parallel, controlled	Country: United Kingdom Funding: Pharm. ind. grant Tx Setting: Unknown Multicenter
Cowie, Revitt, Underwood, et al., 1997	Randomized; parallel, controlled	Country: Canada Funding: Hospital Tx Setting: Primary/specialty combination, university Multicenter
Cote, Cartier, Robichaud, et al., 1997	Randomized; parallel, controlled	Country: Canada Funding: Pharm. ind. grant Tx Setting: Specialty care, nonuniversity Multicenter
Optimal medical management + PFM action plan	use (without action plan) vs. optima	al medical management + PFM-based
Ignacio-Garcia and Gonzalez-Santos, 1995	Randomized; parallel, controlled	Country: Spain Funding: Not specified Tx Setting: Specialty care, nonuniversity
Charlton, Antoniou, Atkinson, et al., 1994	Randomized; parallel, controlled	Country: Australia Funding: Pharm. ind. and government and university funding

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Eligibility Comments

Patient eligibility based on symptoms only. Included patients using inhaled corticosteroids <1,000 mcg per day for at least 1 month.

Exclusions: Patients on oral steroids or using peak flow meters at home.

Patient eligibility based on lung function and utilization.

Inclusion: FEV<sub>1</sub> reversibility 20% or greater Exclusion: Patients who already owned a PFM

Patient eligibility based on lung function, symptoms, utilization. Inclusions: PEF variability maximum 0.15%; nights/week with symptoms minimum 3; use of inhaled corticosteroids or sodium cromoglycate for a minimum of 3 months

Patient eligibility based on symptoms and utilization.

Inclusions: Treatment for an exacerbation of asthma in an ER or attending a university asthma clinic; history of receiving urgent treatment for asthma in the previous 12 months

Patient eligibility based on lung function and symptoms.  ${\rm FEV}_1$  postbronchodilator 85-100% of predicted PEF minimum 85% of predicted; PEF variability minimum 0%; Methacholine

Exclusion: Patients having previously taken part in an asthma educational program

Power based on several outcomes (FEV needed 23 patients, sixfold reduction in night wakening needed 21 per group, eightfold reduction in days off work or school needed 37 per group).

2-week course of oral steroids given before randomization to optimize lung function.

Power based on the 569 randomized, but n varies for each outcome and in some cases is not specified as to exact n, just that n was > = 250; may not be powered for all outcomes.

Patients included had less severe asthma on entry than those who already owned a PFM and were excluded, especially with regard to social and physical functioning.

Doctor also graded the overall and individual severity of symptoms as 0 = none and 3 = severe.

Subjects were recruited by contacting those who had been treated for an exacerbation of asthma in an emergency room or those attending a university asthma clinic with a history of having received urgent treatment for their asthma in the previous 12 months.

In discussion "although the control group received more than the usual care treatment, none received book, none had written action plan; none had structured education or PFM at home after run-in."

Run-in = 2-6 wks.; diagnosis of asthma included need to take daily anti-inflammatory agents; were excluded.

Patient eligibility based on utilization only.

Inclusion: Patients from outpatient asthma clinic with asthma for 2 years

Patient eligibility based on utilization only.

Inclusion: Patients who required admission for asthma or attended the outpatient department

One doctor aware of the group assignment was responsible for assessment of all patients' condition, but the paper also says "in control group, the doctor assessing the patient was blinded with regard to registers of peak flow monitoring until end of study"; random allocation by order of recruitment.

Randomization was based on age, sex, whether they used asthma prophylaxis before study.

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TABLE 2–2. Lung Function Outcomes: FEV<sub>1</sub>

Citation	Study Arm	Number Enrolled	Number Evaluable	Treatment Duration (weeks)
Usual care vs. peak flow meter (PFM)-base	d action plan			
Jones, Mullee, Middleton, et al., 1995	Usual care	64	39	26
	PFM-based action plan	63	33	26
Drummond, Abdalla, Beattie, et al., 1994 (GRASSIC)	Usual care	284	260	52
	PFM-based action plan	285	250	52
Ayres, Campbell, and Follows, 1995	Usual care	64	64	24
	PFM-based action plan	61	61	24
Cowie, Revitt, Underwood, et al., 1997	Usual care	48		
	PFM-based action plan	46		
Cote, Cartier, Robichaud, et al., 1997	Usual care	54		
	PFM-based action plan	50		
Usual care + PFM use alone vs. usual care	+ PFM-based action plan			
Ignacio-Garcia and Gonzalez-Santos, 1995	Usual care + PFM use	44	35	28
	Usual care + PFM-based action plan	1 50	35	28
Charlton, Antoniou, Atkinson, et al., 1994	Usual care + PFM use	43		
	Usual care + PFM-based action plan	d 48		

Source: Blue Cross and Blue Shield Association Technology Evaluation Center. *Management of Chronic Asthma: Evidence Report/Technology Assessment Number 44.* AHRQ Publication No. 01–EO44. Rockville, MD: Agency for Healthcare Research and Quality. September 2001.

Baseline FEV <sub>1</sub> *	Final FEV <sub>1</sub>	P- Value	P-Value Comparison	Comments
85.4 +/- 17.5 % of predicted	81.2 +/- 18.3 % of predicted			
87.1 +/- 16.9 % of predicted	83.2 +/- 18 % of predicted	NS	Absolute value, Tx vs. Ctl	
78.1 % of predicted	75.4 +/- 27.7 % of predicted			95% CI for baseline FEV is 74.8–81.
77.3 % of predicted	74.6 +/- 27.8 % of predicted	NS	Change, Tx vs. Ctl	95% CI for baseline FEV is 74.1–80.5
2 +/- 0.1 L (type predose)	2.2 +/- 0.1 L (type predose)		•	Unclear number of patients analyzed on each end point.
2.3 +/- 0.1 L (type predose)	2.3 +/- 0.2 L (type predose)	NS	Absolute value, Tx vs. Ctl	Unclear number of patients analyzed on each end point.
78 +/- 21.3 % of predicted				Number of subjects with <0% predicted was 10.
82 +/- 20.5 % of predicted				Number of subjects with <60% predicted was 9.
65.34 +/- 16.6 % of predicted (type predose)	65.48 +/- 24.7 % of predicted			
69.03 +/- 24.0 % of predicted (type predose)	80.45 +/- 23.3 % of predicted	< 0.0040	Absolute value, Tx vs. Ctl	

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TABLE 2-3. Symptom Score Outcomes

Citation	Study Arm	Number Enrolled	Number Evaluable	Treatment Duration (weeks)	Baseline Daytime Symptom Score	Final Daytime Symptom Score
Usual care vs. peak flow	v meter (PFM)	)-based act	tion plan			
Jones, Mullee, Middleton, et al., 1995	Usual care	64	45	26		4.95 (median; scale, 0–3)
	PFM-based action plan	63	39	26		2.85 (median; scale, 0–3)
Drummond, Abdalla, Beattie, et al., 1994	Usual care	284	67	52		
	PFM-based action plan	285	54	52		
Ayres, Campbell and Follows, 1995	Usual care	64	64	24	1.91 +/- 0.6 (scale, 0–3)	1.39 +/- 1.11, (scale, 0–3)
	PFM-based action plan	61	61	24	1.77 +/- 0.6 (scale, 0–3)	1.38 +/- 0.12, (scale, 0–3)
Cowie, Revitt, Underwood, et al., 1997	Usual care	48	48	24		
	PFM-based action plan	46	46	24		
Cote, Cartier, Robichaud, et al., 1997	Usual care PFM-based action plan	54 50				
Usual care + PFM use al	lone vs. usua	l care + PFI	M-based act	ion plan		
Ignacio-Garcia and Gonzalez-Santos, 1995	Usual care + PFM use	44	35	28		
	Usual care + PFM-based action plan	50	35	28		
Charlton, Antoniou, Atkinson, et al., 1994	Usual care + PFM use	43	37	52		0.22 (median; scale, 0–3)
Themson, or an, 1777	Usual care + PFM-based action plan	48	42	52		0.26 (median; scale, 0–3)

Source: Blue Cross and Blue Shield Association Technology Evaluation Center. *Management of Chronic Asthma: Evidence Report/Technology Assessment Number 44.* AHRQ Publication No. 01–EO44. Rockville, MD: Agency for Healthcare Research and Quality. September 2001.

P-Value	Final Nighttime Symptom Score	P-Value	Comments
	0.75 (median; scale, 0–3)		Symptom score across study was divided by number of days w/diary data X 28 to give a monthly rate; sx score day = cough; sx score night = wakening at night; median wheeze = 5.46; shortness of breath = 7.88; asthma restricting normal daily activities = 0.0.
NS1	0.35 (median; scale, 0–3)	NS <sup>1</sup>	Symptom score across study was divided by number of days w/diary data X 28 to give a monthly rate; sx score day = cough; sx score night = wakenings at night; median wheeze = 4.39; shortness of breath = 6.50; asthma restricting normal daily activities = 0.17.  Night and day sx score outcome is only from a subgroup of patients reporting variation in outcome; 112/246 never reported sleep disturbances; 15/246 reported that their sleep was disturbed every night.  Night and day outcome is only from a subgroup of patients reporting variation in outcome, controlled for peak flow, FEV <sub>1</sub> , duration of asthma; 114/239 never reported sleep disturbances; 14/239 reported that their sleep was disturbed every night.
	0.69 +/- 0.13, (scale, 0–3)		Sx score day = overall severity of asthma. Changes in: sleep disturbance scores $1.89 \rightarrow 0.69$ ; cough at rest $1.08 \rightarrow 0.69$ ; wheeze at rest was $1.25 \rightarrow 0.67$ ; difficulty breathing $1.47 \rightarrow 0.96$ ; cough with activity = $1.75 \rightarrow 1.30$ .
NS1	0.67 +/- 0.14, (scale, 0–3)		Sx score day = overall severity of asthma.  Changes in: sleep disturbance scores 1.79 → 0.67; cough at rest 1.00 → 0.87; wheeze at rest was 0.97 → 0.74; difficulty breathing 1.41 → 0.85; cough with activity = 1.48 → 1.28. All comparisons in sx scores between groups NS.  No significant differences in other indexes of asthma control, including waking with asthma, beta₂-agonist use, or self-rating of asthma severity differed among the groups at 3 months or at 6 months after entry.  No significant differences in other indexes of asthma control, including waking with asthma, beta₂-agonist use, or self-rating of asthma severity among the groups at 3 months or at 6 months after entry.
			Nighttime symptoms = total nighttime awakenings over total study. (Values not reported by AHRQ) Nighttime symptoms = total nighttime awakenings over total study.
NS <sup>1</sup>	0.25 (median; scale, 0–3) 0.15 (median; scale, 0–3)	NS <sup>1</sup>	Sx score day = wheeze day; Sx score night = wheeze night; daily score for activity restriction was 0.13.  Sx score day = wheeze day; Sx score night = wheeze night; daily score for activity restriction was 0.06, p <0.05 compared to control.

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# PEAK FLOW-BASED COMPARED TO SYMPTOM-BASED WRITTEN ACTION PLANS

### Question

Compared to a written action plan based on symptoms, does use of a written action plan based on peak flow monitoring improve outcomes?

### **Summary Answer to the Question**

Evidence neither supports nor refutes the benefits of written action plans based on peak flow monitoring compared to symptom-based plans in improving health care utilization, symptoms, or lung function. Just four studies, one including children, were available, and these studies had limitations (e.g., inadequate sample sizes and power to detect differences or potential bias in patient selection). The evidence does not clearly show that a peak flow-based action plan is better, but equivalent benefits have been demonstrated (Evidence B). Patient preferences and circumstances (e.g., inability to recognize or report signs and symptoms of worsening asthma) may warrant choosing peak flow monitoring.

The NAEPP EPR-2 recommendations have not been changed. It is the opinion of the Expert Panel that peak flow monitoring for patients with moderate or severe persistent asthma should be considered because it may enhance clinician-patient communication and may increase patient and caregiver awareness of the disease status and control (Evidence B).

### Rationale for the Question

The EPR-2 contains descriptions of the data available to assess asthma-related outcomes associated with peak flow monitoring. The EPR-2 Panel made clear that studies conducted at the time of EPR-2 were limited in number and quality and that findings were contradictory. Some guidance was available in the existing research related to patients with moderate or severe asthma who might benefit most from peak flow monitoring. It was considered useful to search the literature for additional, more recent studies.

Efforts to teach, encourage, and persuade patients to use a peak flow meter can be costly. Review of the question would help discern whether physician and patient time, energy, and money are warranted in terms of disease-related outcomes.

### Systematic Review of the Evidence

The following description of the systematic review of the evidence (SRE) is an adaptation of the evidence report, including direct excerpts, submitted by the Blue Cross Blue Shield Association Evidence-Based Practice Center. (See Introduction, Methods.)

# Methods of Literature Search

The evidence review included studies that lasted at least 12 weeks and that compared the use of a peak flow

meter-based plan plus medical management vs. a symptom-based action plan plus medical management, different schedules of peak flow monitoring, or the use of peak flow monitoring for routine chronic management vs. acute exacerbations. The comparison of peak flow monitoring to symptom monitoring was considered a strong approach, as there is widespread agreement among clinicians that patients should closely monitor their asthma symptoms. Peak flow monitoring values are thought to be beneficial objective measures that help patients determine the need to adjust their medicines and identify potentially urgent situations. Their use in patient self-management is thus dependent on an action plan provided by a clinician. Therefore, all studies included in the SRE compared peak flow monitoring-based written action plans with symptombased written action plans.

# Summary of Findings

#### **Studies**

Four studies met SRE inclusion criteria to assess the differences in outcomes when using a peak flow monitoring-based written action plan or a symptom-based action plan. (See the key evidence tables in this section). None of the studies met SRE criteria for high quality. In addition, the studies included in the review had significant limitations (e.g., all four studies had insufficient power to detect differences between treatment and control groups). Further methodological weaknesses were noted in the question on written action plans, because three of the studies were included in both reviews (Cowie et al. 1997, Cote et al. 1997, and Charlton et al. 1990).

# Results of Studies

Three of the four studies documented no significant differences on any outcome measure between peak flow monitoring—based plans and symptom-based plans. One study reported a difference in total emergency department visits in favor of the peak flow monitoring—based plan (Cowie et al. 1997). These findings are presented in the key evidence tables at the end of this section. However, the significant methodologic weaknesses of the studies, as noted earlier, limit the conclusions. For example, the study reporting reduced emergency department visits did not compare change from baseline among groups, and the data suggest the effect may be attributable to a subset of patients who had very high frequency of emergency department visits.

In summary, the available evidence neither supports nor refutes the use of peak flow monitoring-based action plans vs. symptom-based plans in improving outcomes.

### **Recommendations for EPR Update**

Current EPR-2 recommendations should not be changed until there is clear evidence that one monitoring method is superior to another. The Expert Panel recommends the following shaded text be incorporated into EPR-2.

# Component 1: Measures of Assessment and Monitoring; Peak Flow Monitoring (pages 28 through 33 in EPR-2)

Peak flow monitoring can be used for short-term monitoring, managing exacerbation, and daily long-term monitoring. When used in these ways, the patient's measured personal best is the most appropriate reference value. Thus far, the few studies that have isolated a comparison of peak flow and symptom monitoring have not been sufficient to assess the relative contributions of each to asthma management. The literature does suggest which patients may benefit most from peak flow monitoring. (See box 1, Peak Flow Monitoring Literature Review.)

A systematic review of the evidence conducted in 2002 concluded that evidence at this time does not clearly show that a peak flow monitoring—based action plan is better than a symptom monitoring—based plan in improving outcomes, but it does show similar benefits (SRE-Evidence B). In the opinion of the Expert Panel, there are two distinct arguments for keeping the recommendations to consider peak flow monitoring for patients with moderate or severe persistent asthma: (1) peak flow monitoring appears to provide a way to enhance clinician-patient communication, and (2) either peak flow or symptom self-monitoring appears to increase patient awareness of the disease status and control, thereby helping patients "tune in" to their disease.

If this is the case, either method, if taught and followed correctly, may be equally effective (Evidence B). Patient preferences for objective measures or certain patient circumstances, such as inability to either perceive or report signs and symptoms of worsening asthma, warrant the use of peak flow monitoring. It is the opinion of the Expert Panel that the associated clinician and patient time, energy, and costs are, therefore, justified (Evidence D). This does not, however, change the recommendation that all patients with persistent asthma have a peak flow meter and know how to use it.

The Expert Panel concludes, on the basis of this literature and the Panel's opinion, that:

- Patients with moderate or severe persistent asthma should learn how to monitor their PEF and have a peak flow meter at home.
- Peak flow monitoring during exacerbations of asthma is recommended for patients with moderate or severe persistent asthma to:
  - Determine severity of the exacerbation
  - Guide therapeutic decisions (see component 3, Managing Exacerbations, and figure 4–5) in the home, clinician's office, or emergency department.
- Long-term daily peak flow monitoring is helpful in managing patients with moderate or severe persistent asthma to:
  - Detect early changes in disease status that require treatment
  - Evaluate responses to changes in therapy
  - Provide assessment of severity for patients with poor perception of air flow obstruction
  - Afford a quantitative measure of impairment.
- If long-term daily peak flow monitoring is not used,

- a short-term (2- to 3-week) period of peak flow monitoring is recommended to:
- Evaluate responses to changes in chronic maintenance therapy.
- Identify temporal relationship between changes in PEF and exposure to environmental or occupational irritants or allergens. It may be necessary to record PEF 4 or more times a day (Chan-Yeung 1995).
- Establish the individual patient's personal best PEF.
- The Expert Panel does not recommend long-term daily peak flow monitoring for patients with mild intermittent or mild persistent asthma unless the patient, family, and/or clinician find it useful in guiding therapeutic decisions. Any patient who develops severe exacerbations may benefit from peak flow monitoring (Evidence B).

Limitations of long-term peak flow monitoring include:

- Difficulty in maintaining adherence to monitoring (Reeder et al. 1990; Chmelik and Doughty 1994; Malo et al. 1993), often due to inconvenience, lack of required level of motivation, or lack of a specific treatment plan based on PEF
- Potential for incorrect readings related to poor technique, misinterpretation, or device failure.

Whether peak flow monitoring, symptom monitoring, or a combination of approaches is used, the Expert Panel believes that self-monitoring is important to the effective self-management of asthma. The nature and intensity of self-monitoring should be individualized, based on such factors as asthma severity, patient's ability to perceive or report airflow obstruction, availability of peak flow meters, and patient preferences.

# **Recommendations for Future Research**

The utility of peak flow monitoring and the circumstances where it is beneficial continue to be salient issues in asthma self-management. The following questions for research deserve attention:

- Does peak flow monitoring provide benefits over symptom monitoring? Studies of adequate power are needed to settle the question.
- Which patients (e.g., those with more severe disease, of different ages, or with special circumstances or preferred language or literacy concerns) are most likely to benefit from peak flow monitoring? Studies in children are especially needed because children may not report symptoms as easily or readily as adults.
- What type of benefits can be accrued from peak flow monitoring?
  - Identification of precipitants to symptoms?
  - More timely adjustment of medicines?
  - Improved perception of airflow obstruction?
- Is peak flow monitoring more likely to be used by patients regularly instead of only during exacerbations?
   Short-term vs. long-term? What are the relative benefits of short-term use in producing disease-related outcomes?

The SRE stimulates questions that go beyond those related to written action plans and peak flow vs. symptom monitoring. Answers to the following related and

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# **Key Evidence Tables**

**TABLE 2-4. Study Characteristics** 

Citation	Study Design	Study Setting
PFM-based action plan vs. symptom-based	action plan	
Cowie, Revitt, Underwood, et al., 1997	Randomized; parallel, controlled	Country: Canada Funding: Foothills Hospital, Calgary
		Tx Setting: Primary/specialty combination, university Multicenter
Cote, Cartier, Robichaud, et al., 1997	Randomized; parallel, controlled	Country: Canada Funding: Pharm. Ind., grant Tx Setting: Specialty care,
		nonuniversity Multicenter
Turner, Taylor, Bennett, et al., 1998	Randomized; parallel, controlled	Country: Canada Funding: Pharm. Ind. + other, not specified
		Tx Setting: Primary care, nonuniversity
Charlton, Charlton, Broomfield, et al., 1990	Randomized; parallel, controlled	Country: United Kingdom Funding: Clare Wand Fund, Scientific Foundation of RCP Vitalogap Tx Setting: Specialty care, nonuniversity

Source: Blue Cross and Blue Shield Association Technology Evaluation Center. *Management of Chronic Asthma: Evidence Report/Technology Assessment Number 44.* AHRQ Publication No. 01–EO44. Rockville, MD: Agency for Healthcare Research and Quality. September 2001.

TABLE 2-5. Lung Function Outcomes: FEV<sub>1</sub>

Citation	Study Arm	Number Enrolled	Number Evaluable	Treatment Duration (weeks)
Peak flow meter (PFM)–based action pla	an vs. symptom-based act	ion plan		
Turner, Taylor, Bennett, et al., 1998	Symptom-based action plan	48	48	24
	PFM-based action plan	44	44	24
Charlton, Charlton, Broomfield, et al., 1990	Symptom-based action plan PFM-based action plan			
Cowie, Revitt, Underwood, et al., 1997	Symptom-based action plan	45		
	PFM-based action plan	46		
Cote, Cartier, Robichaud, et al., 1997	Symptom-based action plan	45		
	PFM-based action plan	50		

<sup>\*</sup>  $\ensuremath{\mathsf{FEV}}_1$  pre- or postbronchodilator status unknown unless otherwise indicated.

Source: Blue Cross and Blue Shield Association Technology Evaluation Center. *Management of Chronic Asthma: Evidence Report/Technology Assessment Number 44.* AHRQ Publication No. 01–EO44. Rockville, MD: Agency for Healthcare Research and Quality. September 2001.

Eligibility	Comments
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Patient eligibility based on symptoms and utilization.

Inclusions: Treatment for an exacerbation of asthma in an ER or attending a university asthma clinic; history of receiving urgent treatment for asthma in the previous 12 months

Subjects were recruited by contacting those who had been treated for an exacerbation of asthma in an emergency department or those attending a university asthma clinic with a history of having received urgent treatment for their asthma in the previous 12 months.

Patient eligibility based on lung function and symptoms. FEV $_1$  Postbronchodilator 85-100% of predicted; PEF minimum 85% of predicted; PEF variability minimum 0%; Methacholine Exclusion: Previous enrollment in an asthma educational program

In discussion "although the control group received more than the usual care treatment, none received book, none had written action plan, none had structured education or PFM at home after run-in"; run-in = 2–6 weeks; diagnosis of asthma included need to take daily anti-inflammatory agents; were excluded.

Patient eligibility based on lung function and symptoms.

Inclusions: Methacholine PC20 maximum 7.9; using inhaled corticosteroids

Patients were randomized after stratification for severity of airway responsiveness using values of PC20 methacholine <2 mg/mL or ≥2 mg/mL.

Exclusions: Previous PFM use; significant comorbid conditions

150 screened, 117 enrolled.

Patient eligibility based on symptoms only. Inclusion: Patients on repeat prescribing register Patients were not randomly selected for participation. Letters were sent to patients on the repeat prescribing register, and invited them to make an appointment with a nurse.

P-Value					
Baseline FEV <sub>1</sub> *	Final FEV <sub>1</sub>	P-Value	Comparison	Comments	
78.7 +/- 18.9% of predicted	86.1 (mean) of predicted			FEV <sub>1</sub> in L, mean (SD) was 2.86 (0.88).	
78.1 +/- 19.7% of predicted	83 (mean) % of predicted	NS	Absolute value, Tx vs. Ctl	FEV <sub>1</sub> in L, mean (SD) was 2.84 (0.86).	
79 +/- 18% of predicte	ed			Number of subjects with <60% predicted was 8	
82 +/- 20.5% of predic	eted			Number of subjects with <60% predicted was 9	

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**TABLE 2-6. Symptom Score Outcomes** 

Citation		Number Enrolled	Number Evaluable	Treatment Duration (weeks)	Baseline Daytime Symptom Score
Peak flow meter (PFM)–based actio	on plan vs. symptom-	based ac	tion plan		
Turner, Taylor, Bennett, et al., 1998	Symptom-based action plan	48	48	24	9.1 (mean; scale, 0–24)
	PFM-based action plan	44	44	24	8.2 (mean; scale, 0–24)
Charlton, Charlton, Broomfield, et al., 1990	Symptom-based action plan PFM-based action plan				
Cowie, Revitt, Underwood, et al., 1997	Symptom-based action plan	45	45	24	
	PFM-based action plan	1 46	46	24	
Cote, Cartier, Robichaud, et al., 1997	Symptom-based action plan	45			
	PFM-based action plan	n 50			

<sup>&</sup>lt;sup>1</sup>Treatment comparison-absolute value, Tx vs. Ctl

Source: Blue Cross and Blue Shield Association Technology Evaluation Center. *Management of Chronic Asthma: Evidence Report/Technology Assessment Number 44.* AHRQ Publication No. 01–EO44. Rockville, MD: Agency for Healthcare Research and Quality. September 2001.

important research questions may enhance efforts to educate patients and foster self-management:

- Which components of self-management interventions are most powerful (i.e., account for the greatest variance in disease-related outcomes)?
- What is the minimum core of information and skills required in self-management interventions to produce desired outcomes?
- Which types of interventions (and which of their components) are most effective given the patient's disease severity?
- Which members of the health care team or education partners (e.g., teachers and social workers) best provide which components of self-management education?
- What new venues (e.g., worksites, community centers, churches) might provide greater access to patients who are members of underserved populations?

#### REFERENCES

- Blue Cross and Blue Shield Association Technology Evaluation Center.

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<sup>&</sup>lt;sup>2</sup>Treatment comparison not specified